

Public Health Service, HHS

§ 73.19

inspect and copy any records relating to the activities covered by this part.

§ 73.17 Notification for theft, loss, or release.

(a) Upon discovery of a theft or loss of a select agent or toxin, an entity required to register under this part must immediately notify the HHS Secretary and State and local law enforcement. The notification must be reported to the HHS Secretary by either telephone, facsimile, or e-mail in accordance with § 73.21.

(b) Thefts or losses must be reported whether the select agent or toxin is subsequently recovered or the responsible parties are identified.

(c) When reporting a theft or loss, the entity must provide the following information:

(1) The name of the select agent or toxin and any identifying information (*e.g.*, strain or other characterization information);

(2) An estimate of the quantity lost or stolen;

(3) An estimate of the time during which the theft or loss occurred; and

(4) The location (building, room) from which the theft or loss occurred.

(d) The entity shall immediately notify the HHS Secretary and State and local public health agencies of any release of a select agent or toxin causing occupational exposure or release outside of the primary containment barriers. The report must be made to the HHS Secretary by telephone, facsimile, or e-mail in accordance with § 73.21.

(e) When reporting a release, the entity must provide the following information:

(1) The name of the select agent or toxin and any identifying information (*e.g.*, strain or other characterization information);

(2) An estimate of the quantity released;

(3) The time and duration of the release;

(4) The environment into which the release occurred (*e.g.*, in building or outside of building, waste system);

(5) The location (building, room) from which the release occurred;

(6) The number of individuals potentially exposed at the facility.

(7) Actions taken to respond to the release; and

(8) Hazards posed by the release.

(f) Within seven calendar days of theft, loss, or release, the entity must submit a follow-up report in writing to the HHS Secretary on CDC Form 0.1316 in accordance with § 73.21.

§ 73.18 Administrative review.

An entity may obtain review of a decision denying or revoking a certificate of registration under § 73.7 and the affected entity or individual may obtain review of a decision denying or revoking approval under § 73.8 by requesting such review in writing within 30 calendar days after the adverse decision. The request for review must state the factual basis for the review, which will be carried out in accordance with 42 U.S.C. 262a(e)(7). Where the adverse decision is in whole or in part based upon notification by the Attorney General under 42 U.S.C. 262a (e)(3), the request for review will be forwarded to the Attorney General for the Attorney General's review and final notification to the HHS Secretary.

§ 73.19 Civil money penalties.

(a) The Inspector General of the Department of Health and Human Services is delegated authority to conduct investigation and to impose civil money penalties against any individual or entity in accordance with regulations in 42 CFR part 1003 for violation of the regulations in this part, as authorized by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107-188). The delegation of authority includes all powers contained in section 6 of the Inspector General Act of 1978 (5 U.S.C. App.).

(b) The administrative law judges in, assigned to, or detailed to the Departmental Appeals Board (DAB) have been delegated authority to conduct hearings and to render decisions with respect to the imposition of civil money penalties, as authorized by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107-188). This delegation includes, but is not limited to, the authority to administer oaths and affirmations, to subpoena witnesses and